510(k) SUMMARY
Nidek ECHOSCAN Model US-1800

1. SUBMITTER INFORMATION

A.	Company Name:	Nidek Incorporated
B.	Company Address:	47651 Westinghouse Drive. Fremont, CA 94539-7474
C.	Company Phone: Company Fax:	(510) 353-7722 (510) 226-5750
D.	Contact Person:	Mr. Hiro Matsuzaki Quality Assurance Manager Nidek Incorporated
E.	Date Summary Prepared:	March 13, 2002

2. DEVICE IDENTIFICATION

A.	Classification Name:	Ultrasonic Pulsed Echo Imaging System
B.	Trade/Proprietary Name:	Nidek ECHOSCAN Model US-1800
C.	Device Classification:	Class II (per 21 CFR 892.1560)
D.	Product Code:	IYO

3. SUBSTANTIAL EQUIVALENCE

The Nidek Incorporated US-1800 device is of comparable type and is substantially equivalent to the following predicate device:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
ECHOSCAN Model US-2000	Nidek Co. Ltd.	K903326	11-21-90

4. DEVICE DESCRIPTION

The EchoScan Model US-1800 is a diagnostic instrument that is indicated for use in the measurement of the axial length of the eye and corneal thickness.

The instrument is used to measure the axial length of the eye and the thickness of the cornea by the application of an ultrasound pulse reflection method. During axial length measurement, the cornea is touched with a probe, and the ultrasonic pulse sent by the transducer in the probe is reflected within each part of the eye (cornea, anterior chamber, lens, vitreous body, retina, etc.) and their echoes are received by the same probe. The received echoes are converted to electronic acoustic signals and indicated on the LCD as an amplitude. In addition, the time difference of each echo is measured and the length of each tissue (AC depth, lens thickness, vitreous body length, and axial length) is calculated according to the time difference and known inherent sonic velocity of each tissue.

For corneal thickness measurement, the ultrasonic pulses are transmitted when the probe is put on the cornea. Part of the pulses are reflected and the front and rear surface of the cornea. When the probe receives the reflected echoes, the time difference of each echo is measured and the corneal thickness is calculated according to the time difference and known inherent sonic velocity of the cornea.

5. INTENDED USE

The Nidek ECHOSCAN Model US-1800 is a diagnostic instrument that is intended for use in the measurement of the axial length of the eye and corneal thickness.

6. TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Nidek Model US-1800 and the predicate device Model US-2000 has been performed, and the results are summarized in the table below. The results of this comparison demonstrate that the Nidek Model US-1800 uses the same fundamental scientific technology and as the predicate device Model US-2000. The differences between the Nidek Model US-1800 and the predicate device are insignificant and do not affect the safety or effectiveness of the device.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS: US-1800 VS. US-2000

	Predicate Device Model US-2000 (K903326)	**Model US-1800**
AXIAL LENGTH MEASUREMENT:		
Probe Type	Solid Probe	Solid Probe
Frequency	10 MHz Transducer	10 MHz Transducer
Internal Fixation	LED (Red)	LED (Red)
Measuring System	Ultrasonic Pulse Reflection Method	Ultrasonic Pulse Reflection Method
Measurable Value	Axial Length, Anterior Chamber Depth, Lens Thickness, Vitreous Length	Axial Length, Anterior Chamber Depth, Lens Thickness, Vitreous Body
Clinical Accuracy	± 0.1 mm	± 0.1 mm
Measurable Range	36 mm	12 to 40 mm
Amplifier Gain	Variable	Variable
Converted Ultrasonic Velocity	Axial Length:1550m/s (Phakic eye) 1532m/s (Aphakic Eye) Anterior Chamber: 1532 m/s Lens Thickness: 1641 m/s Vitreous Body: 1532 m/s	Axial Length: 1550 m/s (Phakic Eye) 1532 m/s (Aphakic Eye) 2760 m/s (PMMA Pseudophakic Eye) Anterior Chamber: 1532 m/s Lens Thickness: 1641 m/s Vitreous Body: 1532 m/s
IOL Power Calculation	Binkhorst, Holladay, Modified Regression II	Hoffer-Q, Holladay, Binkhorst, SRK, SRK-II, SRK-T
Display Resolution	0.01 mm	0.01 mm
CORNEAL THICKNESS MEASUREMENT:		
Probe Type	Gel-Coupled Probe	Solid Probe
Frequency	11 MHz	11 MHz
Probe Tip Size	1.5 mm Diameter	1.5 mm Diameter

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS: US-1800 VS. US-2000

	Predicate Device Model US-2000 (K903326)	**Model US-1800**
Measuring System	Ultrasonic Pulse Reflection	Ultrasonic Pulse Reflection
Measuring Point	33 Points (max.)	33 Points (max)
Accuracy	± 5μm	± 5μm
Measuring Range	200 to 1300 μm	200 to 1300 μm
Converted Ultrasonic velocity	1640 m/s	1640 m/s
Display resolution	1μm	1μm
Measuring Formats	10 Programmable Formats	10 Programmable Formats
Monitor	CRT 5.5 inches	Color LCD 10.4 inches (640 x 480 dots)
Printer	Thermal Printer	Graphic Thermal Printer
Power Requirements	100, 120, 220, or 240VAC 50 or 60Hz, Less than 100VA	115VAC, 50 or 60Hz, 50VA or less
Dimensions	Main Body: 378 (W) x 300 (D) x 300 (H) mm Keyboard: 370 (W) x 185 (D) x 38 (H) mm	312 (W) x 262.5 (D) x 202.5 (H) mm
Weight	14 Kg	6 Kg

ACOUSTIC FIELD EMISSIONS COMPARISON:

	Water	In Situ	Water	In Situ
AXIAL LENGTH MEASUREMENT PROBE:				
Spatial Peak-Temporal Average Intensity (mW/cm2)	0.612	0.083	0.000531	0.0000734
Spatial Peak-Pulse Average Intensity (W/cm2)	7.55	1.02	1.48	0.205
CORNEAL THICKNESS MEASUREMENT PROBE:				
Spatial Peak-Temporal Average Intensity (mW/cm2)	0.501	0.45	0.0186	0.0186
Spatial Peak-Pulse Average Intensity (W/cm2)	14.58	13.0	1.38	1.38

7. PERFORMANCE DATA

The following testing was performed on the Nidek Model US-1800 to demonstrate that it meets all specified requirements and is equivalent to the predicate device:

A. Electrical Safety Testing & Electromagnetic Compatibility

The Nidek Model US-1800 was tested in accordance with EN 60601-1 and EN 60601-1-2, and was found to meet all requirements of both standards.

B. Programmable Electrical Medical Systems

The Nidek Model US-1800 was tested in accordance with EN 60601-1-4 and was found to meet all requirements of the standard.

C. Acoustic Output Test Measurements

The Nidek Model US-1800 was tested in accordance with the Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (May 1998). The acoustic field emissions for the Model US-1800 were lower than the acoustic emissions for the predicate device Model US-2000.

8. CONCLUSIONS

Nidek Incorporated has demonstrated through its evaluation of the Nidek Model US-1800 that the device is equivalent to the predicate device with respect to intended use, technological characteristics, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 3 2002

Nidek Incorporated
% Ms. Carol L. Patterson
Consultant
Patterson Consulting Group, Inc.
21911 Erie Lane
LAKE FOREST CA 92630

Re: K020876
Trade Name: Nidek EchoScan Model US-1800
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYO and 90 ITX
Dated: March 28, 2002
Received: April 3, 2002

Dear Ms. Patterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the EchoScan Model US-1800, as described in your premarket notification:

Transducer Model Number

A-Scan Probe
Pachymetry Probe

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Nidek Echoscan Model US-1800 System

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	P									
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020876

A-Scan Probe

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Diagnostic Ultrasound Indications for Use Form

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Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	P									
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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F-3**510(k) Number** K020876

Pachymetry Probe

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Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	P									
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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